DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2007

Curasan AG, Frankfurt Facility
C/O Mr. Eric Weichert
President
Applications Specialist International, Incorporated
109 Shore Drive
Garner, North Carolina 27529

Re: K051443
Trade/Device Name: Cerasorb® Dental, Cerasorb® M Dental, and Cerasorb® Perio
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: May 31, 2005
Received: June 2, 2005

Dear Mr. Weichert:

This letter corrects our substantially equivalent letter of August 3, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 (http://www.fda.gov/cdrh/organiz.html#OC for OC organization structure). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Cerasorb® M DENTAL

Indications for Use

510(k) Number (if known): K051443

Device Name: Cerasorb® M DENTAL

Indications for Use:

Cerasorb® M DENTAL is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RSBetz DDS for Dr. Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051443

1.4 Statements of Indications for Use

Cerasorb® DENTAL

Indications for Use

510(k) Number (if known): K051443

Device Name: Cerasorb® DENTAL

Indications for Use:

Cerasorb® DENTAL is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of perio-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number:

Cerasorb® Perio

Indications for Use

510(k) Number (if known): K051443

Device Name: Cerasorb® Perio

Indications for Use:

Cerasorb® Perio is recommended for:

- Filling and/or reconstruction of non-infected periodontal bone defects in conjunction with other products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of infrabony periodontal defects
- Filling of single-or multi-wall bone pockets.
- Filling of bifurcations and trifurcations

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JUL 2 2 2005

curasan

K051443

Abbreviated 510 (k) Summary:

Cerasorb® DENTAL
Cerasorb® M DENTAL
Cerasorb® Perio

1. SUBMISSION INFORMATION

Name and Address of the Sponsor:	curasan AG Lindigstrasse 4 63801 Kleinostheim Germany
Contact person:	Dr. Wolf-Dietrich Huebner, MD Medical Director Tel.: +49 – 6027 – 4686-325 Fax: +49 – 6027 – 4686-433 E – Mail: wolf.huebner@curasan.de
Registered U. S. Agent:	Dr. Eric Wiechert, Ph.D. 109 Shore Drive Garner, NC 27529, USA Phone: 919 – 772-8518, fax: 919 – 772-1300 E – Mail: ewiecher@bellsouth.net

2. DEVICE IDENTIFICATION

Proprietary Name:	Cerasorb® DENTAL Cerasorb® M DENTAL Cerasorb® Perio
Common Name:	Bone Void Filler, Synthetic
Classification Name:	Bone Grafting Material, Synthetic
Classification:	Class II, Special Controls
Classification regulation Number:	21CFR 872.3930
Product Code:	LPK, Tricalcium Phosphate Granules for Dental Bone Repair

3. PREDICATE DEVICES

Cerasorb® DENTAL: PMA800035
PerioGlas®: K992416, K040278
BIO-OSS®, BIO-OSS® BLOCKS, BIO-OSS® Collagen: K033815
BIO-OSS® Anorganic Bovine Bone: K970321

4. INTENDED USE

Cerasorb® DENTAL and Cerasorb® M DENTAL are recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge
- Filling of infrabony periodontal defects
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of the maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of perio-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

Cerasorb® Perio is recommended for:

- Filling and/or reconstruction of non-infected periodontal bone defects in conjunction with other products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of infrabony periodontal defects
- Filling of single-or multi-wall bone pockets
- Filling of bifurcations and trifurcations

5. DESCRIPTION OF THE DEVICE

Cerasorb® DENTAL, Cerasorb® M DENTAL and Cerasorb® Perio are a sterile, synthetic, porous and biocompatible ceramic matrix in either granular form (Cerasorb DENTAL), polygonal shaped morsels (Cerasorb M DENTAL) or polygonal broken granulate (Cerasorb Perio). All designs consist of pure-phase Beta-Tricalcium Phosphate with a phase purity of = 99% and comply with the ASTM F 1088-04. The devices, when applied to a bony defect, create a network of large, smoothly interconnected pores providing different porosities (Cearsorb DENTAL approx. 35%, Cerasorb M DENTAL approx. 65 vol% [total porosity] and Cerasorb Perio approx. 25vol%).
The different designs are manufactured by a validated manufacturing process which guarantees batch to batch conformity and reproducibility. Due to their synthetic nature all Cerasorb designs do not pose any risk of potential allergic reactions and are neither locally nor systemically toxic.
In contact with vital bone the Cerasorb granules, morsels or granulate is resorbed and gradually replaced by new bone.

Cerasorb DENTAL, Cerasorb M DENTAL and Cerasorb Perio are provided in double sterile packages (sterilization via gamma irradiation) and are for single-use only.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

Cerasorb DENTAL, Cerasorb M DENTAL and Cerasorb Perio are substantially equivalent to a number of currently marketed and approved/cleared bone void fillers for defects in the oral/maxillofacial and dental region, such as Cerasorb DENTAL (the sponsors own device formally regulated as a PMA, PMA800035), BIO-OSS® Anorganic Bovine Bone (K970321, K033815) and PerioGlas® (K992416, K040278).
Although the source of the material is different (Beta-Tricalcium Phosphate vs. Bovine Bone vs. synthetic bioactive glass material), the intended use, recommended indications for use, target population, anatomical site, and performance data for the three Cerasorb designs and the predicate devices are essentially similar. Also, all materials are resorbable and biocompatible. In contact with vital bone any of the bone grafting materials is resorbed and gradually replaced by new bone.
Information provided in this submission proves the effectiveness and safety of the Cerasorb designs compared to the predicate devices.

7. STATEMENT OF TECHNOLOGICAL COMPARISON

All Cerasorb design modifications consist of pure phase Beta-Tricalcium Phosphate ceramic material according to ASTM F 1088-04. The material is of interconnecting porosity, osteoconductive and resorbable.